UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,451	03/09/2004	Adnan Badwan	85943.8276	2422

22242 7590 07/18/2008
FITCH EVEN TABIN AND FLANNERY
120 SOUTH LA SALLE STREET
SUITE 1600
CHICAGO, IL 60603-3406

EXAMINER	
MAHYERA, TRISTAN J	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
07/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/796,451	BADWAN ET AL.	
	Examiner	Art Unit	
	TRISTAN J. MAHYERA	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Applicant's remarks and amendments filed on 4/14/2008.

Status of the Claims

Claims 1-13 are pending. Claims 3 and 14-19 have been cancelled. Claims 1, 2 and 4-13 have been amended. Claims 1, 2 and 4-13 are examined on the merits.

Claim Rejections - 35 USC § 112

The rejection of Claims 1 and 8 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby **withdrawn** in view of the Applicant's amendments.

Claim 1 is **newly** rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 1 has been amended to incorporate a "second acid source", however, the specification does not describe, mention or convey any possession of a "second acid source". **This is a new matter rejection**.

Claim Rejections - 35 USC § 102

The statute under this section can be found in a prior office action.

The rejection of Claims 1, 3-9 and 11-13 under 35 U.S.C. 102(b) as being anticipated by KATDARE et al. (US 4,639,458) is hereby **withdrawn in light of Applicant's amendments**.

Response to Arguments

Applicant's arguments with respect to claim1, 3-9 and 11-13 have been considered but are moot in view of the new ground(s) of rejection.

Furthermore, in regards to applicant's general argument that KATDARE fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., bioavailability, see Applicant's arguments page 5) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The other properties and limitations (e.g. water content, binders/fillers and lubricants) were addressed in a prior office action.

Claim Rejections - 35 USC § 103

The statutes under this section can be found in a prior office action.

The rejection of Claims 2 and 10 under 35 U.S.C. 103(a) as being unpatentable over KATDARE et al. (US 4,639,458) in view of STORM et al. (US 7,250,176) is hereby **withdrawn in light of the amendments**.

Claims 1, 2 and 4-14 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over ANZAGHI (WO 02/39992) in view of STROM (US 7,250,176).

ANZAGHI teaches quinolonic antibacterial agents for use in oral pharmaceutical compositions. The quinolonic antibacterial agents are between 40 and 80% by weight of the total adduct. See claims 1 and 4. The quinolonic agent adduct can be filtered, spraydried giving a powder form and with the addition of suitable excipients used as granules or tablets. See example 1, claim 16 and claim 17. The quinolonic agent can further be norfloxacin, see claim 7 and example 1. In example 1, ANZAGHI also combines the quinoline agent with an inorganic acid, hydrochloric acid.

ANZAGHI does not teach a concentration of 10% to 35% wt/wt stabilizer in amended claim 1. ANZAGHI does not further teach the use of anhydrous citric acid as the second acid source or sodium starch glycollate as the disintegrant.

STORM describes using a high dose of amoxicillin in a tablet form to treat bacterial infections. STORM also describes an immediate release form consisting of a coating or bilayer and a core formed by wet or dry granulation. The immediate release layer is described as a disintegrant and specifically contains sodium starch glycollate. See col 12 lines 48-63, example 1, 4 and 5; instant claims 1 and 9-11. Anhydrous citric acid as a stabilizer (i.e. release retarding agent/excipient) is disclosed in claims 23, 37,

106, 131 for use in tablet formulations, for example granules, (see example 5) and at a molar ratio (active to anhydrous citric acid) from 100:1 to 1:10 (see col. 14 lines 45-52) that reads on the 10 to 35% limitation. While STROM does not explicitly teach all the instant claimed percentages (e.g. STROM teaches a mole ratio), it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising anhydrous citric acid, sodium starch glycollate and norfloxacin, as taught by ANZAGHI in view of STROM. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of a stabilizer or release retarding excipient on improving the release characteristics of the active in the composition and subsequent tablet as well as the benefits of a stable

disintegrant, as taught by STROM. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Claims 1, 2 and 4-13 are **newly** rejected under 35 U.S.C. 103(a) as being unpatentable over KATDARE (US 4,639,458) in view of STROM.

KATDARE teaches a direct compression quinoline carboxylic acid tablet utilizing non-hydrated quinoline carboxylic acid. See col 1 lines 1-5. The tablet in KATDARE comprises norfloxacin and minimal amounts of other processing aids with no water added. See col 1 lines 58-60. The tablet formulation contains less than 2% water, see col 2 line 20. The processing aids include a disintegrant, a filler/binder and a lubricant See col 1 lines 53-63. Specifically, the filler is microcrystalline cellulose (13-18.5%) the lubricant is magnesium stearate (0.5-2%) and the disintegrant is croscarmellose sodium (1-4.5%). The tablet can be coated by conventional means, see e.g. col 1 lines 64-66.

KATDARE does not teach a concentration of 10% to 35% wt/wt stabilizer in claim 1. KATDARE does not further teach the use of anhydrous citric acid as the second acid source stabilizer or the use of sodium starch glycollate as a disintegrant. However, KATDARE does motivate one to include processing aids, see col 3 lines 58-60.

STORM teaches using a high dose of amoxicillin in a tablet form to treat bacterial infections. STORM also teaches an immediate release form consisting of a coating or bilayer and a core formed by wet or dry granulation. The immediate release layer is taught as containing a disintegrant, specifically sodium starch glycollate. See col 12

lines 48-63, example 1, 4 and 5; instant claims 1 and 9-11. Anhydrous citric acid is further taught as a stabilizer (i.e. release retarding agent/excipient) in claims 23, 37, 106, 131 for use in tablet formulations, for example granules, (see example 5) and at a molar ratio (active to anhydrous citric acid) from 100:1 to 1:10 (see col. 14 lines 45-52) that reads on the 10 to 35% limitation. While STROM does not explicitly teach all the instant claimed percentages (e.g. STROM teaches a mole ratio), it is the position of the Examiner that it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine suitable percentages through routine or manipulative experimentation to obtain the best possible results, as these are variable parameters attainable within the art.

Moreover, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456; 105 USPQ 233, 235 (CCPA 1955). Applicants have not demonstrated any unexpected or unusual results, which accrue from the instant percentage ranges.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to make a composition comprising anhydrous citric acid, sodium starch glycollate and norfloxacin, as taught by KATDARE in view of STROM. One of ordinary skill in the art at the time the invention was made would have been motivated to combine these elements into a single composition because of the beneficial effects of

a stabilizer or release retarding excipient on improving the release characteristics of the active in the composition and subsequent tablet as well as the benefits of a stable disintegrant, as taught by STROM. Absent any evidence to the contrary, and based upon the teachings of the prior art, there would have been a reasonable expectation of success in practicing the instantly claimed invention.

Response to Arguments

Applicant's arguments filed 4/14/2008 have been fully considered but they are not persuasive. Applicants argue that the STROM reference does not cure the deficiencies of KATDARE and adds nothing to the rejection. As stated in the earlier office action and reiterated here, the stabilizer, specifically anhydrous citric acid is found in STORM which adds to the combination of KATDARE and to the combination of ANZAGHI by improving the release retarding properties of the active as suggested in STROM. STROM additionally addresses limitations in the dependent claims, e.g. the use of sodium starch glycollate as discussed above. Thus, by the reasonable combination of the prior art, the present invention which is a composition comprising the active norfloxacin, anhydrous citric acid and the disintegrant sodium starch glycollate is rendered obvious.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tristan J. Mahyera whose telephone number is 571-270-1562. The examiner can normally be reached on Monday through Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tristan J Mahyera/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615